Medicaid Pricing and Rebates 2.0 Complexities and Challenges

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Roadmap

- Quick Recap of Medicaid & Basics of the Medicaid Drug Rebate Program
- Diving Into the Complexities & Challenges
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  - ✓ The 5(i) AMP Calculation
  - ✓ Bundled Arrangements
  - ✓ Smoothing Methodology for Lagged Price Concessions
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Quick Recap of Medicaid

What is Medicaid?

Medicaid provides health coverage to millions of Americans, including eligible low-income adults, children, pregnant women, elderly adults and people with disabilities.

How Medicaid Works

Medicaid is a joint state and federal program that provides health coverage to people with limited income and resources.

It is an entitlement program meaning anyone meeting income and eligibility requirements can enroll.

Dept. of Health & Human Services/Centers for Medicare & Medicaid Services is the federal agency that administers the program

Medicaid Requirements

Federal law requires that all states offer a basic set of benefits and cover certain groups of patients.

Outside of this basic federal framework, states may set their own rules and requirements. These rules and requirements are subject to change by state authorities.

For this reason, Medicaid programs can vary from state to state and enrollment in one Medicaid program does not guarantee enrollment in any other Medicaid program.

Managed Care Organizations

Managed Medicaid plans are quasi governmental plans subject to many of the same federal regulations as traditional Medicaid.

Pharmacy suppliers/providers contract directly with MCOs to provide services within these plans.

The MCOs can set additional requirements for participation in their plans.

Enrollment in the underlying state Medicaid program, and compliance with the state Medicaid requirements, is a prerequisite to contracting with an MCO.

Medicaid Drug Rebate Program: The Basics

- Manufacturers seeking Medicaid reimbursement for their covered outpatient prescription drugs must participate in the program.
- Manufacturers sign a national rebate agreement with HHS in which CMS agrees to cover their products under Medicaid.
- Manufacturers submit certain drug pricing data 30 days after each quarter to calculate the applicable drug rebate.
- Rebate is shared between the state and federal government to help offset the cost of drugs dispensed to Medicaid enrollees.

Both AMP and Medicaid Best Price are used to calculate the Medicaid Drug Rebate

The **Average Manufacturer Price (AMP)** is the average price paid to the manufacturer for the drug by (i) wholesalers for drugs distributed to retail communities pharmacies, and (ii) retail community pharmacies that purchase drugs directly from the manufacturer.

Medicaid Best Price is the lowest price available from manufacturer to any wholesaler, retailer, provider, HMO, non-profit entity or government entity, though certain exceptions apply.

Basic Medicaid Drug Rebate for Innovator Products = Total Units x Greater of (AMP - Best Price) **or** 23.1% of AMP

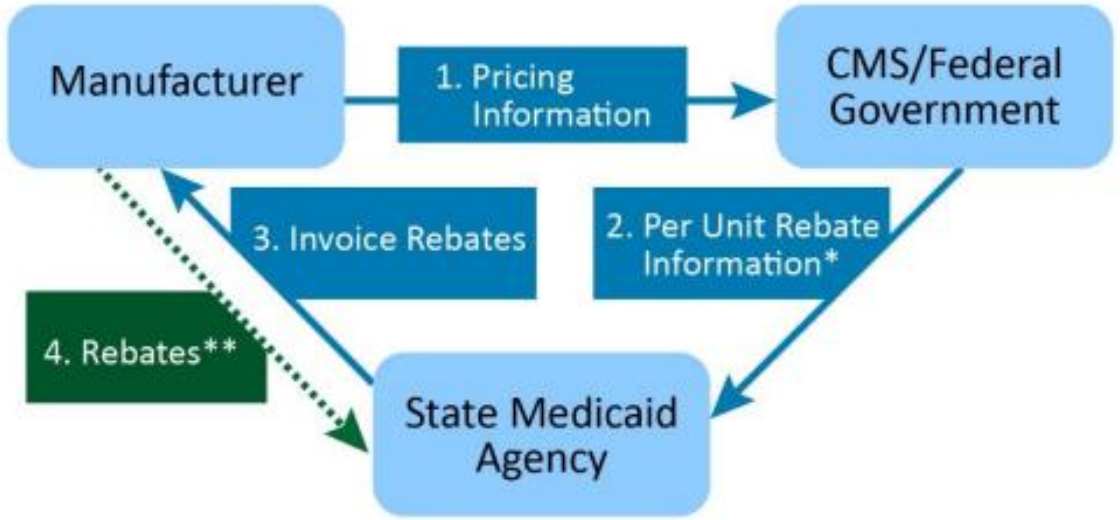
Basic Medicaid Drug Rebate for Non-Innovator Products = 13% of AMP

Additional Medicaid Drug Rebate for Inflation = Amount by which AMP exceeds the inflation-adjusted "baseline" AMP, which is the AMP reported for the first full quarter of sales after the drug is first marketed (for innovator products) or AMP for the fifth full calendar quarter after which the drug is marketed as a drug other than a brand drug (for non-innovator products), both converted to today's dollars using the CPI-U.

Note: The exact methodology for calculating AMP, best price and the MDRP rebates will vary based on additional factors specific to the type of drug, indications, etc.

Calculation and Collection of Medicaid Drug Rebates *

Figure: Calculation and Collection of Medicaid Drug Rebates



Source: Modified from CMS, *Medicaid Drug Rebate Data Guide for States*, section 1927(b) of the Act.

* Per unit rebate information includes both URAs and UROAs.

** With the exception of offset rebates (which States are prohibited from keeping and which we discuss below), CMS and the States share Medicaid rebates on the basis of each State's FMAP.

* Image is from OIG Report entitled, "CMS Did Not Always Provide Accurate Medicaid Unit Rebate Offset Amounts to State Medicaid Agencies," OIG Report No A-07-17-06074 (May 2018) (available here)

Diving Into the Complexities & Challenges

Medicaid Best Price and AMP Reporting: What Is Included?

AMP includes:

- Sales to wholesalers for drugs distributed to **retail community pharmacies**
  - **Retail community pharmacy** is an independent pharmacy, chain pharmacy, supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy and dispenses medication to the general public at retail prices. Does not include mail order, institutional pharmacies, charitable or not-for-profit pharmacies, government pharmacies or pharmacy benefit managers (PBMs).
- Sales to retail community pharmacies
- Different calculation for 5i drugs generally not dispensed through retail community pharmacies (more on this later).

Medicaid Best Price includes:

- All prices, including applicable discounts, rebates or other transactions that adjust prices either directly or indirectly to best price-eligible entities (wholesaler, retailer, **provider**, HMO, non-profit entity, or US government entity).
  - **Provider** includes a hospital, HMO, MCO or entity that treats or provides coverage or services to individuals for illnesses or injuries or provides services or items in the provision of health care.

Medicaid Best Price and AMP Reporting: What Is Excluded?

CMS recognizes certain exceptions where certain prices or price concessions are **not** factored into Medicaid best price or AMP. These exceptions can be found at 42 C.F.R. § 447.505(c) (for Medicaid best price) and at 42 C.F.R. § 447.504(c) and (e) (for AMP). There is considerable overlap between these exceptions. **Key carve-outs include**:

- Prices charged to certain types of entities operated by the federal government or receiving federal funds
- Prices charged under certain programs, including prices negotiated under MA or Part D and SPAP pricing
- Manufacturer assistance offered to patients through coupons, co-pay assistance, patient refunds or rebates
  - Only applies where the full value is passed to the patient and not to a pharmacy, agent or other entity
- Free goods, but only when not contingent on any purchase
- Customary prompt pay discounts
- Bona fide service fees
- PBM rebates, discounts or other financial transactions (with certain exceptions)

Calculating AMP for 5i Drugs

There is a separate designation within the Medicaid Drug Rebate Program for drugs that are inhaled, infused, instilled, implanted or injected, or the **5i drugs**.

- Manufacturers are responsible for identifying any drugs that qualify as a 5i drug.
- Manufacturers must determine that the 5i drug is "not generally dispensed through a retail community pharmacy," which means that 70% or more of the sales of the drug were to entities other than retail community pharmacies or wholesalers for drugs distributed to these pharmacies.

Since the calculation of AMP is otherwise predicated on prices paid by retail community pharmacies and wholesalers that distribute to these pharmacies, manufacturers must use a different rebate calculation methodology for 5i drugs.

AMP for 5i drugs = Sales and associated discounts, rebates, payments or financial transaction to physicians, PBMs, HMOs, MCOs, insurers, hospitals, clinics, outpatient facilities, mail order pharmacies, long-term care providers, hospices, manufacturers and other entities that do not conduct business as a wholesaler or retail community pharmacy

- CMS recognizes many of the same exclusions that apply to Medicaid best price reporting, but importantly, does not carve-out PBM pricing.

Bundled Arrangements

A **bundled sale** is "any arrangement regardless of physical packaging under which the rebate, discount, or other price concession is **conditioned upon the purchase** of the **same drug**, drugs of **different types** … or **another product or some other performance requirement** … or where the resulting **discounts or other price concessions are greater** than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement."

- Discounts in a bundled sale are **allocated proportionally to the total dollar value** of the units of all drugs or products sold under the bundled arrangement. Bundling works to **smooth out discounts** across all units sold within the arrangement.
- In its December 31, 2020 Final Rule, CMS expressly recognizes **value-based purchasing arrangements** can be reported using the bundled sale approach. This took effect on January 1, 2022.
    - Manufacturers can still choose to report multiple best price points under a VBP, but only if they offer the VBP to all state Medicaid programs (which do not have to participate).

Smoothing Methodology for Lagged Price Concessions

Certain discounts and rebates may not be realized under after the sale of the drug. These are considered "**lagged price concessions**," except that they do not include customary prompt pay discounts.

Lagged price concessions serve to "smooth" subsequent adjustments. Otherwise, there could be wildly inconsistent AMPs from one reporting period to the next.

- Manufacturers use a 12-month rolling percentage to calculate monthly AMP (or if less than 12 months, the total number of months of AMP-eligible sales.
- Monthly AMPs then roll up to a quarterly AMP based on a weighted average.
- There is no need to further revise AMP solely as a result of data pertaining to lagged price concessions.
    - Manufacturers must report revisions to monthly AMP for up to 36 months from the month in which the data were due, except that this is not required if the revision is solely as a result of data pertaining to lagged price concessions.

Smoothing Methodology for Lagged Price Concessions (continued)

Lagged price concessions serve to "smooth" subsequent adjustments. Otherwise, there could be wildly inconsistent AMPs from one reporting period to the next.

Calculation of AMP with Lagged Price Concessions	
Total lagged price concessions over most recent 12-month period	$200,000
Total sales subject to AMP reporting for most recent 12-month period	$600,000
Lagged price concession percentage	$200,000 / $600,000 = 0.3333
Total sales subject to AMP reporting for current month being reported	$50,000 for 10,000 units sold
Net total sales amount for current month	$50,000 - (0.3333 x $50,000) = $3,334
AMP for current month	$33,334 / 10,000 = $3.33340

42 C.F.R. § 447.510(d).

Accounting for Authorized Generics and Biosimilars

An **authorized generic drug** is sold, licensed, or marketed under **a new drug application** (NDA) approved by the FDA that is marketed, sold or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the brand name drug.

The **primary manufacturer** holds the NDA of the authorized generic, and the **secondary manufacturer** is authorized by the primary manufacturer to sell the drug (but does not hold the NDA).

- CMS previously directed primary manufacturers to include in their calculation of AMP for brand name drugs the sale of authorized generics to secondary manufacturers ("transfer sale"). The definition of "wholesaler" included secondary manufacturers.
- This leads to bigger reductions in AMP, which in turn leads to lower Medicaid rebates. The OIG determined Medicaid received 36% less in rebates than it otherwise would have for a sample of 9 drugs it reviewed, amounting to $595 million in a single year.
- Now, authorized generic drug transactions to secondary manufacturers are excluded from the AMP calculation of the brand name drug. There should be separate AMPs for the brand name drug and the authorized generic, and the AMP for the brand must exclude sales of the authorized generic.

Accounting for Authorized Generics and Biosimilars (continued)

A **biosimilar** is a biological product that is highly similar and has no clinically meaningful differences from an existing FDA-approved referenced product. Importantly, while biosimilars and generics are versions of brand name drugs, a biosimilar is not a generic drug (and not an authorized generic for the purposes of the Medicaid Drug Rebate Program).

Biosimilars fall within the definition of single source drugs for Medicaid best price reporting purposes. This is due to the fact that biosimilars are licensed under biological license applications (BLAs), which in turn are included in the definition of single source drugs found at 42 C.F.R. § 447.502.

"***Single source drug*** … includes a covered outpatient drug that is a biological product **licensed, produced, or distributed under a biologics license application** approved by the FDA."

"Generally, both reference biological products and biosimilar biological products are licensed under biological license applications (BLA) under section 351 of the PHS Act. For purposes of the Medicaid Drug Rebate (MDR) program, the definition of single source drugs found at 42 CFR 447.502 includes covered outpatient drugs licensed under a BLA. Therefore, in light of this provision, biosimilar biological products fall within the definition of single source drugs in the MDR program."

Medicaid Drug Rebate Program notice dated March 30, 2015. See also MDRP notice dated December 21, 2016.

The HHS Secretary announced that CMS's Innovation Center has been directed to accelerate biosimilar adoption in a report published in February 2023 – with a specific focus on, "1) aligning biosimilar cost-sharing and payment incentives for providers and beneficiaries; 2) creating shared savings arrangements and/or payment bundles for therapeutic classes; and 3) adjusting payment methods to increase competition and promote investment in biosimilar development."

Alternative Rebate Calculation for Line Extensions

Historically, **line extensions** of existing drugs were treated as new drugs. Manufacturers could avoid some of the inflation-based rebates because they did not have to account for increases in price of the original drug (if those increases outpaced inflation). Effective January 1, 2022, CMS will define the term, broadening the types of drugs that must be considered a line extension, and will set forth an alternative rebate calculation.

- **Line extension** means a **new formulation** of a drug, but does not include an abuse-deterrent formulation.
- **New formulation** means a "change to the drug, including but not limited to: an extended release formulation or other change in release mechanism, a change in dosage form, strength, route of administration, or ingredients."

42 C.F.R. § 447.502. *See also* Section 1927(c)(2)(C) of the Social Security Act.

If the original brand name drug is an **oral solid dosage form**, for a line extension of that drug, the manufacturer would use the following alternative rebate calculation if greater than the standard rebate formula that would apply:

Basic Medicaid Rebate + AMP of the line extension x highest inflation-based rebate for any strength of the original brand drug x total number of units of each dosage form and strength of the line extension

The above is **required** if the manufacturer of the line extension also manufacturers to the original brand, or has a **corporate relationship** with the manufacturer of the original brand.

Questions

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